NFI-35 12/1/97

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DEPARTMENT OF HEALTH & HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

PHILADELPHIA DISTRICT

900 U.S. Customhouse
2nd and Chestnut Streets
Philadelphia, PA 19106

Telephone: 215-597-4390

98-PHI-02

WARNING LETTER

November 5, 1997

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

GEN. SPEC.
RELEASE
F# _____ DATE _____
Reviewed by: Mm M. Kaupe

Leonard Camnitz, D.O.
Chief of Mammography
Castor Radiology, P.C.
7310 Castor Avenue
Philadelphia, PA 19152

Inspection ID: 2097420003

Dear Dr. Camnitz:

Your facility was inspected on October 21, 1997, by a representative from the U.S. Food & Drug Administration. This inspection revealed that your facility failed to comply with the Quality Standards for Mammography (Standards) as specified in Title 21, Code of Federal Regulations (CFR), Part 900.12(a)(3), as follows:

> **The Medical Physicist, [redacted] was neither state licensed nor approved, nor board certified, and did not have the education, training, and experience required to perform mammography surveys.**

The attached inspection report was fax'd to you on November 5, 1997. The two level 3 observations listed in this report should also be corrected. Please describe the corrective action you have taken to correct these level 3 items when you respond to this letter.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Mammography Quality Standards Act of 1992 and regulations under the Act. The specific violation noted in this letter and in the printed summary of test results and inspection observations issued at the close of the inspection may be symptomatic of serious underlying problems in your facility's quality assurance program for mammography. You are responsible for investigating and determining the causes of the violations identified by the FDA. If the causes are determined to be deviations from the quality standards, you must promptly initiate permanent corrective actions.

Failure to promptly correct these deficiencies may result in regulatory action being initiated by the Food and Drug Administration without further notice. A facility may be subject to civil money penalties up to $10,000 for each failure to substantially comply with, or each day on which a facility fails to substantially comply with the Standards. A facility may also have its certificate suspended or revoked for failure to comply with the Standards. Continuation of any activity related to the provision of mammography by a facility that constitutes a serious risk to human health may result in injunction.

You should be advised that FDA regulations do not prevent enforcement of requirements under State laws and regulations. You may receive a letter or notification from the Commonwealth of PA advising you of this fact.

Please notify this office in writing, **within 15 working days of receipt of this letter,** of the specific steps you have taken to correct the noted violations. Also include an explanation of each step being taken to prevent the recurrence of similar violations.

Your response should be sent to:

Robert E. Davis, Investigator
U.S. Food & Drug Administration
7 Parkway Center, Rm 390
Pittsburgh, PA 15220

with a copy to:

David Gaisior
PA Dept. of Environmental Resources
Bureau of Radiation Protection
Lee Park Suite 6010
555 North Lane
Conshohocken, PA 19428

If you have any questions regarding this letter, please call Mr. Davis at 412-644-3394.

Sincerely yours,

Terry D. Condon for

Diana Kolaitis
District Director
Philadelphia District

Attachment: Inspection Report, Inspection ID# 2097420003

cc: David Gaisior
PA Dept. of Environmental Resources
Bureau of Radiation Protection
Lee Park Suite 6010
555 North Lane
Conshohocken, PA 19428